K032286

NOV 2 0 2003

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Tracy J. Bickel
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: Calcigen™ PSI Bone Graft Substitute

Common Name: Bone graft substitute; bone void filler

Classification Name: Resorbable Calcium Salt Bone Void Filler (MQV)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: **Calcigen™ PSI Bone Graft Substitute- K030178 (Biomet, Inc.); WMT-TCP Bone Graft Substitute- K022629 (Wright Medical Technology, Inc.); Cerasorb Ortho- K014156 (Curasan AG); MIIG™ II- K024336 (K022629 (Wright Medical Technology, Inc.).**

Device Description: Calcigen™ PSI bone graft substitute is a resorbable osteoconductive scaffold composed of 60% hydroxyapatite (HA) and 40% tri-calcium phosphate (TCP). The device is available as granules, cubes, or cylinders. Calcigen™ PSI is porous with multidirectional interconnected pores resembling that of cancellous bone.

Indications for Use: Calcigen™ PSI bone graft substitute is indicated for bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. Calcigen™ PSI bone graft substitute can be combined with autogeneous bone marrow aspirate or autogenous blood. Calcigen™ PSI resorbs and is replaced with bone during the healing process.

Summary of Technologies: The technological characteristics (materials, design sizes, and indications) are similar to or identical to that of the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing and literature review determined the device will function as indicated.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Tracy J. Bickel
Regulatory Associate
Biomet Orthopedics, Inc.
P.O Box 587
Warsaw, Indiana 46581-0587

Re: K032286
Trade Name: Calcigen PSI Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 21, 2003
Received: October 17, 2003

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032286
Device Name: **Calcigen™ PSI Bone Graft Substitute**
Indications for Use:

Calcigen™ PSI bone graft substitute is indicated for bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. Calcigen™ PSI bone graft substitute can be combined with autogeneous bone marrow aspirate or autogenous blood. Calcigen™ PSI resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032286